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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,628

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Ruth Barrett

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KLARQUIST SPARKMAN, LLP  
121 SW SALMON STREET  
SUITE 1600  
PORTLAND, OR 97204

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

01/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,628	<b>Applicant(s)</b> BARRETT ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 and 11-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1,2,5,11,13,17-27,29-31 drawn to a method of screening for a first gene that affects a pain state using a *non-transgenic* fish exhibiting a pain state comprising mutating said fish exhibiting a pain state to identify a genetic difference that affects the pain state.

Group II, claim(s) 1,2,6,11,13,17-27,29-31 drawn to a method of screening for a substance that affects a pain state using a *non-transgenic* fish comprising treating said fish exhibiting a pain state with a substance to identify a substance that affects the pain state.

Group III, claim(s) 2,3,12,27-31 drawn to a method of screening for a first gene that affects a pain state using a *transgenic* fish wherein the transgene leads to a pain state comprising mutating said fish exhibiting a pain state to identify a genetic difference that affects the pain state.

Group IV, claim(s) 2,4,27,29-31 drawn to a method of screening for a substance that affects a pain state using a *transgenic* fish wherein the transgene leads to a pain state comprising treating said fish exhibiting a pain state with a substance to identify a substance that affects the pain state.

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Group V, claim(s) 13-16 drawn to a method of screening for a further test substance that affects activity of a protein encoded by the first gene or test substance, once identified, and characterizing said further test substance.

Claims 7-10 are withdrawn and are not considered in the instant restriction requirement because they are wholly unclear. The claims refer to the effect of the second gene or said treatment of claim 1. However, the fish of claim 1 do not recite a second gene or a treatment. It appears that claims 7-10 may have been intended to depend from claim 2.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if the specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product.
- 2) A product and a process of use of said product.

- 3) A product, a special process of manufacture of said product, and a process of use of said product.
- 4) A process and an apparatus specially designed to carry out said process.
- 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In the instant case, the groups are drawn to multiple, distinct methods. Groups are drawn to methods of using two different products, a transgenic fish (Group III and IV) and a non-transgenic fish (Groups I and II). Groups II and IV differ from Groups I and III in that the former are drawn to methods of screening for substances while the latter are drawn to screening for mutant genes. Group V is drawn to a method of screening for a modulator of a gene or substance identified in the methods of any of Groups I-IV, which is a different method from any of Groups I-IV and begins with an identified product or gene. Group IV is drawn to a method of testing for interaction between compounds that is different from the methods of Groups I-IV.

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PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-V, do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “ special technical feature” of Groups III and IV is a transgenic fish having altered pain state. The “ special technical feature” of Groups I and II is a non-transgenic, substance-treated or otherwise treated fish having altered pain state. The “ special technical feature” of Group III is the “ first gene” . Thus, there appears to be no corresponding technical feature common to all groups.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.